

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*
ex rel. JULIE LONG,

Plaintiffs,

V.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No.
16-12182-FDS

**PLAINTIFF’S RESPONSE TO JANSSEN BIOTECH’S OBJECTIONS/REQUEST FOR
RECONSIDERATION OF THE DECEMBER 20, 2021 DISCOVERY RULINGS**

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Janssen's late appeal of multiple rulings set forth in the December 20, 2021 Order (ECF 237), which the Court converted into a motion for reconsideration, should be denied. The Court followed the case management plan, closely considered the proportionality factors, and exercised its discretion in determining that Plaintiff should receive the following ordinary discovery: (1) 12 additional ESI custodians, (2) responsive documents possessed by current and former employees who had significant involvement in the alleged kickback scheme, (3) documents and information that originated after Plaintiff left Janssen but which are relevant to the kickbacks at issue, (4) discovery concerning the scienter elements of Plaintiff's claims, and (5) a complete privilege log identifying relevant legal advice Janssen received as well as any relevant legal assessments it performed. Regardless, faced with having to comply with fundamental discovery obligations that it has been avoiding for over a year and having to provide what amounts to normal discovery for a case of this importance, size, and scope, Janssen has asserted meritless objections in an effort to relitigate the issues and further delay production of this core discovery. However, none of the rulings are legally erroneous, never mind the result of a manifest error. The Court does not misunderstand the case management order, as Janssen asserts. And there is no newly discovered evidence that would require the Court to change any of its rulings. The Court recognizes that it would be manifestly unfair and counterproductive to force Plaintiff to defend summary judgement and present her claims at trial armed with only the limited and incomplete discovery received during the initial phase. Reconsideration of the December 20 rulings should be denied.

I. PROCEDURAL HISTORY

This action, brought on behalf of the United States, seeks to hold Janssen accountable under the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") for the substantial damages it has caused to the Medicare program by engaging in a long-running, nationwide

kickback scheme involving the regular provision of a variety of different types of free infusion business support and advisory programs to select physician practices to induce doctors to prescribe and infuse Remicade and Simponi ARIA (collectively, “IOI Support”). Exercising its discretion, the Court has been closely managing discovery throughout this case. In accordance with the Court’s initial plan, discovery has been an evolving process.

A. The Initial Discovery Stage To Confirm That Janssen In Fact Provided The IOI Support In Central Pennsylvania As Part Of A National Strategy

In deciding Janssen’s motion to dismiss, the Court held that Plaintiff’s complaint alleges with sufficient particularity that Janssen engaged in a nationwide kickback scheme that caused physicians to submit false claims to Medicare. *See* ECF 75 at 33. In its decision, the Court indicated that it would undertake an initial discovery process similar to that utilized in two other cases in order “to probe the validity of the kickback allegations before considering whether to authorize nationwide discovery.” *Id.* at 33 n.12 (quoting *U.S. ex rel. Carpenter v. Abbott Lab’ys, Inc.*, 723 F. Supp. 2d 395, 409-10 (D. Mass. 2010) and citing *U.S. ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008)).

Thereafter, at the scheduling conference, the Court, consistent with its motion to dismiss ruling, set an expedited initial discovery period to probe the validity of the allegations that the IOI Support was in fact provided in Central Pennsylvania (the territory Plaintiff covered while working as an Area Business Specialist (“ABS”)) under a national directive. *See* Dec. 14, 2020 Scheduling Conf. Tr. (ECF 90) at 4:6-4:22; 10:6-11:5. The Court also created this short initial phase to “inform a whole bunch of issues ... about how discovery ought to proceed and what makes sense under the circumstances, and then examine that in another two or three months, and then in all likelihood continue to expand the scope of discovery” *Id.* at 4:18-4:22.

Although the first stage was to only last three months and be completed by March 22,

2021, *see* ECF 89, the period was extended to November 15, 2021 at Janssen's request to give it additional time to produce requested documents. *See* ECF 134.

B. During The Initial Phase, The Court Substantially Limited Plaintiff's Discovery While It Assessed Whether The Evidence Supports The Allegations That Janssen Provided The IOI Support In Central Pennsylvania Under A National Directive And Determined How Future Discovery Should Be Structured

As Plaintiff described in substantial detail in her motion to compel filed on March 8 (ECF 100), in the three addendums to that motion filed on April 23 (ECF 121), May 7 (ECF 129), and July 9 (ECF 149), the motion to compel filed on August 6 (ECF 159), and the addendum to that motion filed on October 13 (ECF 189), throughout the first stage Janssen refused to provide most of the discovery Plaintiff requested, claiming it was outside the limitations the Court set during the December 14, 2020 scheduling conference. At the time those motions were filed, the case was in the first phase in which discovery was heavily focused on confirming that the alleged kickbacks (*i.e.*, the IOI Support) were provided in Central Pennsylvania under a national directive. In accordance with the Court's instructions concerning the purpose and parameters of the first stage and maintaining that phase's short schedule, Chief Magistrate Judge Kelley denied several aspects of Plaintiff's discovery motions, substantially limiting the discovery she received during the initial phase and providing her with what amounts to small samples of the evidence she requested. The Court limited the number of custodians to a small number of witnesses. It limited discovery to just a portion of the relevant period. And it postponed some of the discovery Plaintiff was seeking related to certain issues, including the scienter elements. All this was done to ensure that the first phase could be completed before the scheduled end date. Moreover, the Court postponed this discovery understanding that the assessment at the end of the first stage would be limited to confirming that the IOI Support was provided in Plaintiff's former territory under a national directive and would not involve a summary judgment type review of all

elements of Plaintiff's claims. And in denying Plaintiff requested discovery, the Court made it clear that she could renew her requests after the first stage was complete.

C. The Case Moves To The Second Stage Where Plaintiff Can Obtain Full Discovery Concerning All Issues Except For Field-Level Activities In Other Territories And Afterwards The Court Will Conduct A Bellwether Summary Judgment Evaluation

On October 22, the Court provided instructions regarding the second stage of the Court's case management plan. As part of the second phase, the Court created a bellwether summary judgment process through which it will evaluate whether the evidence sufficiently supports Plaintiff's allegations that Janssen's provision of the free IOI Support to physician practices violated the AKS and FCA. The pre-trial bellwether will take place after the parties have completed discovery concerning all elements of Plaintiff's claims and be focused on the IOI Support provided to physician practices in Central Pennsylvania. *See* Oct. 22, 2021 Status Conf. Tr. (ECF 203) at 11:5-12:10.

While making it clear that Plaintiff can obtain discovery of all aspects of the alleged kickback scheme—from discovery of what was happening in the field in Central Pennsylvania to discovery of Janssen's most senior management's knowledge and involvement in the alleged scheme—the Court imposed a regional limitation on field-level discovery during this second stage. For purposes of this stage, the Court believes it is unnecessary for Plaintiff to obtain discovery concerning details of what ABSs and physicians in other regions were doing because the bellwether is focused on how Janssen caused physicians in Plaintiff's former territory to submit false bills to Medicare for Remicade and Simponi ARIA.

D. Plaintiff's November 26, 2021 Motion Requesting Discovery That She Was Not Allowed To Obtain In The Initial Phase And Her December 3, 2021 Motion To Compel

As part of the transition to the second stage of discovery and bellwether summary judgment process, the Court afforded Plaintiff an opportunity to seek reconsideration of earlier

discovery rulings that Plaintiff believed were no longer applicable under the updated case management plan. *See* ECF 205. Plaintiff filed the motion on November 26 (ECF 218)

(“November 26 Motion”), requesting reconsideration of the following rulings, among others:

- (1) The July 26, 2021 ruling concerning the addition of more custodians (*see* July 26, 2021 Order (ECF 155); July 26, 2021 Hearing Tr. (ECF 157) at 37:4-37:17);
- (2) The May 6 and October 18, 2021 rulings concerning production of relevant discovery that post-dates February 2016 (*see* Oct. 18, 2021 Order (ECF 194); Oct. 18, 2021 Hearing Tr. (ECF 201) at 34:5-34:11; May 6, 2021 Hearing Tr. (ECF 131) at 22:24-23:6); and
- (3) The July 26 and October 18, 2021 rulings postponing discovery concerning Janssen’s scienter and intent, including the legal advice it received concerning the lawfulness of providing the free services at issue to physician practices to induce utilization and sales of Remicade and Simponi ARIA (*see* Oct. 18, 2021 Hearing Tr. (ECF 201) at 10:4-11:2; July 26, 2021 Order (ECF 155); July 26, 2021 Hearing Tr. (ECF 157) at 9:17-9:24).

While the November 26 Motion was pending, Plaintiff filed a motion on December 3 (ECF 223) (“December 3 Motion”) requesting that Janssen be ordered to provide:

- (1) A complete log identifying all documents withheld under a claim of privilege; and
- (2) Documents responsive to Plaintiff’s requests that are in the possession of current and former employees who had significant involvement in Janssen’s provision of the IOI Support and who are known to have discoverable information.

On December 20, the Court heard oral argument on the November 26 Motion and December 3 Motion. After hearing argument and considering the briefing, the Court issued an order setting forth its rulings concerning the relief requested in the November 26 Motion as well as certain relief requested in the December 3 Motion (“December 20 Order”). *See* ECF 237.

Rather than comply with the rulings in the December 20 Order, Janssen objected to them. Its untimely notice of appeal filed on January 10 asserts the following objections¹:

- (1) The decision partially granting Plaintiff’s request for additional ESI custodians;

¹ Inasmuch as the appeal was filed after the Court’s 6:00 p.m. deadline, it is untimely and can be denied on that ground alone.

- (2) The decision ordering Janssen to produce responsive documents possessed by current and former employees who had significant involvement in the IOI Support strategy and scheme;
- (3) The decision partially granting Plaintiff's request that responsive documents that post-date February 2016 be produced;
- (4) The decision clarifying that Plaintiff is permitted to take full discovery concerning the scienter elements, and as part of that discovery Janssen must produce any legal advice it received concerning the lawfulness of the IOI Support (as well as any legal reviews or analyses its performed or received); and
- (5) The decision ordering Janssen to provide a privilege log identifying any legal advice it received concerning the legality of the IOI Support (as well as any legal reviews or analyses its performed or received) that it is withholding under a claim of privilege.

See ECF 237. On January 13, Chief Judge Saylor granted the notice of appeal in part and referred the matter back to Chief Magistrate Judge Kelley "for reconsideration and clarification in light of the issues raised in the notice of appeal." ECF 256. Thereafter, Chief Magistrate Judge Kelley directed that the brief in support of the motion of appeal be treated as a motion for reconsideration. See ECF 257.

II. LEGAL STANDARD

"[T]he granting of a motion for reconsideration is 'an extraordinary remedy which should be used sparingly.'" *Sullivan v. Dumont*, 391 F. Supp. 3d 161, 165 (D. Mass. 2019) (quoting *CardioFocus, Inc. v. Cardiogenesis Corp.*, 859 F. Supp. 2d 192, 202 (D. Mass. 2012)). A motion for reconsideration will be granted only upon a showing of (1) a "manifest error of law," (2) new evidence, or (3) a misunderstanding or other error "not of reasoning but apprehension." *Abiomed, Inc. v. Maquet Cardiovascular LLC*, 2021 WL 5639206, at *2 (D. Mass. Dec. 1, 2021) (Saylor, J.) (quoting *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 81-82 (1st Cir. 2008)); *In re Schlich*, 2017 WL 1015005, at *1 (D. Mass. Mar. 15, 2017) (Saylor, J); *Shealey v. Federal Ins. Co.*, 946 F. Supp. 2d 193, 201 (D. Mass. 2012) (Saylor, J). A motion for reconsideration "cannot

be used to ‘advance a new argument that could (and should) have been presented prior to the district court’s original ruling.’” *Shealey*, 946 F. Supp. 2d at 201 (quoting *Cochran v. Quest Software, Inc.*, 328 F.3d 1, 11 (1st Cir. 2003)). Such a motion is also not “an appropriate means to ‘repeat old arguments previously considered and rejected.’” *Id.* at 201-202 (quoting *Nat’l Metal Finishing Co., Inc. v. BarclaysAmerican/Commercial, Inc.*, 899 F.2d 119, 123 (1st Cir. 1990)); accord *Ofori v. Ruby Tuesday, Inc.*, 205 F. App’x. 851, 852-53 (1st Cir. 2006) (“simple disagreement with the Court’s decision is not a basis for reconsideration”). Moreover, when a party objects to a decision involving a discovery dispute, magistrate judges are afforded great deference and the decision should only be reversed for an abuse of discretion. *See Benefit Mgmt. of Maine, Inc. v. Allstate Life Ins. Co.*, 993 F.2d 1530, 1993 WL 177120, at *2 (1st Cir. 1993); *Sullivan v. Experian Info. Solutions, Inc.*, 2020 WL 7625177, at *1 (D. Mass. Nov. 16, 2020); *Ellison v. American Nat. Red Cross*, 151 F.R.D. 8, 9-10 (D.N.H. 1993).

None of the factors that would warrant reconsideration of the December 20 Order apply.

III. ARGUMENT

A. The Court Should Deny Reconsideration Of Its Ruling Allowing The Addition Of 12 ESI Custodians

In the December 20 Order, the Court granted in part Plaintiff’s request that Janssen be required to perform ESI searches of additional employees’ files. *See* ECF 237. The Court allowed Plaintiff to select 12 additional custodians, rather than 28 as requested. *See id.* The Court explained that it “finds that this is warranted because relator has had an evolving understanding of who the key custodians are and this number is appropriate given the scope of the case.” *Id.*

Janssen objects to the ruling, arguing that the Court failed to follow the case management plan. In particular, Janssen asserts (incorrectly) that Plaintiff is barred from obtaining document discovery from anyone who was not in her “direct chain-of-command,” which, according to

Janssen, is limited to just two positions—the regional business manager (“RBM”) and regional business director—and excludes mid- and senior-level managers and employees in the compliance, marketing, business analytics, and ABS training departments. *See* ECF 252 at 6.

During the October 22, 2021 status conference, Chief Judge Saylor provided clear instructions concerning the updated case management plan. Chief Magistrate Judge Kelley has conferred with Chief Judge Saylor concerning the case management plan. In addition, Janssen presented its unreasonable interpretation of the case management plan in its briefing and during oral argument, and the Court rejected it.

To be sure, under the current plan, Plaintiff is restricted from seeking field-level discovery (*i.e.*, documents detailing ABSs’ delivery of the IOI Support and related interactions with physician practices) related to territories other than Central Pennsylvania. Consequently, Plaintiff cannot obtain documents possessed by other ABSs and RBMs who were not assigned to the Central Pennsylvania territory.

Recognizing that senior managers and employees in the compliance, marketing and other departments possess information that is highly relevant to the claims and defenses, when the Court allowed three additional custodians as part of its July 26, 2021 order, it declined to impose a chain-of-command restriction. *See* ECF 155. Tellingly, Janssen did not object to that ruling. Plaintiff selected a mid-level marketing manager (Mike Wolfe), a senior-level marketing manager (Scott White), and a compliance officer (Edmund Greenidge). Plaintiff has also deposed Mr. Wolfe, even though he was not in Plaintiff’s so-called “direct chain-of-command.” Janssen’s assertion that, in allowing Plaintiff to select 12 additional custodians from the list of 28 employees set forth in her complaint, the Court misunderstood or disregarded the case management plan simply has no merit.

Trying to relitigate the decision, Janssen also asserts that in partially granting Plaintiff's motion for additional custodians, the Court made a clear legal error because it determined that allowing 12 custodians was proportional to the needs of the case. *See* ECF 252 at 6-9. The Court's decision did not constitute a legal error – never mind an error that is manifest.

The Court granted Plaintiff's motion in part, allowing her to add only 12 employees as custodians, not all 28 employees she identified and requested in the motion. *See* ECF 237. That Chief Magistrate Judge Kelley allowed Plaintiff to add less than half the number of employees she requested as custodians, demonstrates a close consideration of whether the request was proportional to the needs of the case. Likewise, the explanation in the December 20 Order that “[t]he court finds that this is warranted because relator has had an evolving understanding of who the key custodians are and this number is appropriate given the scope of the case” further demonstrates that the Court considered the proportionality factors.

The Court reviewed that parties' briefing on the issue, including Plaintiff's analysis of each of the Rule 26(b)(1) proportionality factors. *See* ECF 219 at 13. In response, Janssen argued that the documents from the 13 custodians (including Plaintiff), along with the documents that were originally produced to the Department of Justice, which included documents from 10 custodians that included ABSs and RBMs (none of whom were responsible for the Central Pennsylvania territory), was an adequate amount of discovery for this case. *See* ECF 227 4-6. Significantly, even though under Rule 26(b)(2)(B) it was Janssen's burden to show that adding ESI custodians is unduly burdensome or expensive, it did not provide any such evidence.

And at oral argument, during which Janssen again argued Plaintiff has been afforded sufficient discovery, the Court gave close consideration to proportionality and specifically commented on the importance of this discovery in resolving the issues in the case. *See* Dec. 20,

2021 Hearing Tr. (ECF 259) at 11:8-11:17.

The Court, which is well familiar with the case management plan, the numerous discovery disputes, the discovery that has been exchanged, and the associated burdens, concluded that allowing 12 more custodians is proportional to the case’s needs – a case in which Janssen admits that a very large number of employees have relevant documents (*see* ECF 232 at 6). In exercising its discretion, the Court did not make a clear error of law.

With its objections to the December 20 Order, Janssen submitted an untimely declaration from an attorney at Janssen’s parent, Johnson & Johnson, concerning the time and expense incurred in producing the documents during the initial stage and estimates of the time and expense that will be involved in producing documents from 12 additional custodians (“Mosquera Declaration”). The information in this declaration is not newly discovered. Janssen was aware of the time and expenses associated with discovery in this case long before it submitted its brief opposing the addition of more ESI custodians on December 3. Because this is not new evidence, the Mosquera Declaration should not be considered. *See U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 2021 WL 5827750, at *1 (D. Mass. Dec. 8, 2021) (Kelley, J).

But even if the Court were to consider this information—it should not—it would not clearly lead to a different result. Janssen through the Mosquera Declaration seeks to show that performing ESI searches of employees’ files has been and will be expensive. Although this is a factor to be considered in reviewing the proportionality of the discovery, the other proportionality factors clearly predominate over Janssen’s cost concerns. As Plaintiff explained in her brief in support of the November 26 Motion:

- “This case, brought and pursued on behalf of the United States, involves a large, nationwide kickback scheme and Medicare fraud and thus is of significant importance.”

- “In light of the number of prescriptions for Remicade and Simponi ARIA and subsequent bills to Medicare that were tainted as a result of Janssen’s provision of the free IOI Support, the amount in controversy is substantial, with damages far exceeding one hundred million dollars.”
- “Janssen has access to the requested custodians’ electronic files, but Plaintiff does not.”
- “Janssen cannot claim to lack the resources to provide this discovery.”
- “The requested documents from a cross-section of employees who held different positions over different stretches of the relevant period, and therefore performed different roles in Janssen’s nationwide, long-running strategy and scheme, are critical to resolving the factual issues in this case.”
- “[T]he importance and benefit of this discovery far outweighs any burden associated with producing the electronic files.”

ECF 219 at 13.

With regard to Janssen’s resources, Plaintiff’s complaint reports that during just the five-year period spanning 2013-2017, which covers only a portion of the damages period, Medicare Part B paid nearly \$6.8 billion for Remicade and Simponi ARIA use by Medicare beneficiaries. *See* ECF 55 at ¶¶48-49, 56-57. Plaintiff alleges that a significant percentage of these reimbursements were the result of the alleged AKS and FCA violations. And so even if Janssen’s asserted estimate turns out to be accurate, that cost is a reasonable amount given the many other factors that make the discovery proportional to the needs of the case, not least the hundreds of millions of dollars Janssen has earned by inducing physicians to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries by providing the free IOI Support.

In addition, as Plaintiff reported in her brief in support of the November 26 Motion, excluding Plaintiff’s documents, Janssen has produced 44,122 documents from the employees who served as custodians. *See* ECF 219 at 11. One third of those documents came for Karen Trahan’s files. These documents were all identified using ESI search queries. Because these documents contained a search term, Janssen merely needed to perform a privilege review before

producing the documents from the custodians (none of whom are attorneys from Janssen's legal department). Although it did not provide a breakdown of its time and expenses, Janssen states that it had 25 contract attorneys spend thousands of hours reviewing these documents over more than six months. While Janssen was free to pay an army of contract attorneys to go over the documents with a fine-tooth comb, that it opted to employ this strategy does not excuse it from producing additional necessary discovery. Were that the standard, well-heeled defendants could easily avoid discovery by paying lawyers to closely review documents and run out the clock.

Regardless, the cost of the production in this case is far from unprecedented. For example, in *John B v. Goetz*, 879 F. Supp. 2d 787, 789 (M.D. Tenn. 2010), the court ordered the defendant to produce ESI with an estimated cost of \$10 million, nearly quadruple the estimate here. And in *CCA Recordings 2255 Litig. v. U.S.*, 2020 WL 4284222, at *6 (D. Kan. July 27, 2020), the defendant was ordered to produce ESI with an estimated cost of over \$3.5 million.

Janssen also baselessly asserts that the Court failed to consider whether the documents possessed by additional custodians are different from those that have been produced. To make this argument, Janssen relies on non-binding decisions from courts outside of the First Circuit that are hardly new law. Tellingly, Janssen did not previously cite these decisions or even assert that the documents possessed by the 28 employees whom Plaintiff identified in her brief (ECF 219 at 11-12) are not unique from the documents produced to date. Since Janssen provided no support for this assertion in its original briefing, let alone raise it, it need not be addressed.

In addition to being procedurally improper, this argument is incorrect. The Court considered Plaintiff's brief in support of her November 26 Motion that explained the relevance and uniqueness of the information possessed by the 28 employees. *See* ECF 219 at 10-13. The IOI Support strategy was a major corporate initiative involving numerous employees across

multiple departments over many years. Janssen’s counsel has referred to this as a “massive case” (July 26, 2021 Hearing Tr. (ECF 157) at 16:17) and has acknowledged there “are lots of people involved” (*Id.* at 40:3-41:8). Importantly, Janssen provided no concrete data that shows all documents and information from the employees would be duplicative of those already produced.

The employees Plaintiff identified in her brief held different positions within the various departments that played a major role in the development, review, approval, and monitoring of the IOI Support services. And, because of the length of time Janssen has been providing the IOI Support, Plaintiff requires documents from additional employees in order to cover the full relevant period. Consequently, the Court did consider Plaintiff’s need for discovery across multiple positions and roles and the length of the relevant period. In the December 20 Order the Court specifically stated that 12 custodians “is appropriate given the scope of the case.” ECF 237. Given the resources and personnel Janssen devoted to the long-running IOI Support strategy and scheme, 25 total ESI custodians (including Plaintiff) is hardly disproportionate. *See, e.g.,* decisions cited on page 12 of Plaintiff’s brief in support of the Nov. 26 Motion (ECF 219); *see also City of Sterling Heights Gen. Emps. Ret. Sys. v. Prudential Fin., Inc.*, 2015 WL 5055241, at *3-4 (D.N.J. Aug. 21, 2015) (finding 76 custodians to be fair based on the number of personnel that had involvement in the alleged securities fraud).²

The Court should deny reconsideration of this ruling because it understands the case management plan, there is no newly discovered evidence, and there was no manifest error of law.

² The cases Janssen cites bear no similarities to the facts and discovery plan in place here. For instance, in *In re Novo Nordisk Sec. Litig.*, 530 F. Supp. 3d 495 (D.N.J. 2021), the court analyzed the number of accountants from a *non-party* auditor whose files should be searched for relevant communications. Significantly, the court found it would be fair to search the files of nearly half the accountants assigned to the audit. *See* 530 F. Supp. at 503-505. Half the accountants with discoverable information is more coverage than was ordered here. And that was for a non-party.

B. The Court Should Deny Reconsideration Of Its Ruling Requiring Janssen To Produce Responsive Documents From The Files Of Current And Former Employees Who Had Significant Involvement In Janssen's Provision Of The Alleged Kickbacks

In the December 3 Motion, Plaintiff requested that Janssen be compelled to comply with its basic discovery obligations and produce documents from the files of current and former employees who had significant involvement in the IOI Support strategy and scheme. *See* ECF 224 at 11-13. Janssen has acknowledged to the Court that it has not produced responsive documents from any employees' files and that the only documents possessed by employees that it has produced are the documents from the ESI searches conducted of the 13 custodians' files. After considering the parties' briefing and arguments during the hearing, as part of the December 20 Order (ECF 237), the Court ordered Janssen to Produce "documents responsive to relator's requests from all sources and not confine itself to the custodians' documents."

As an initial matter, Janssen feigns that it is unsure what the Court meant by "all sources." ECF 252 at 12. However, it is obvious from the Court's order, the discussions during oral argument, Plaintiff's motion and brief, and even Janssen's own opposition that "all sources" refers to all places within Janssen's possession, custody, and control where responsive documents are located including the files of current and former employees. Contrary to Janssen's exaggerations, it is not required to review the files of every current and former employee across the entire Janssen enterprise over a period of two decades. What the Court has clearly ordered with regard to employee documents is that Janssen cannot limit its production to ESI searches. Instead, as the Federal Rules mandate, it must make a reasonable inquiry and undertake a reasonable effort to produce requested documents possessed by current and former employees who had significant involvement in the development, review, approval, monitoring, and/or delivery of the IOI Support. It is a fundamental discovery requirement that a party must produce

documents responsive to a request for production when such documents are in the party's "possession, custody or control." Fed. R. Civ. P. 34. Similarly, counsel must make "a reasonable effort to assure that the client has provided all information and documents available to him that are responsive to the discovery demand." *Legault v. Zambrano*, 105 F.3d 24, 28 (1st Cir. 1997) (quoting the Advisory Committee's Notes to the 1983 Amendments to Rule 26). And by signing the response to a document request, an attorney certifies that to the best of their "knowledge, information, and belief formed after a reasonable inquiry," the disclosure is "complete and correct as of the time it was made." Fed. R. Civ. P. 26(g)(1)(A). Contrary to Janssen's baseless assertions, conducting ESI searches of 12 employees' and Plaintiff's electronic files did not relieve it from its basic obligation to collect and produce documents responsive to Plaintiff's document requests from all sources, including other employees who had significant involvement (including attorneys in the legal department) and from the 13 custodians themselves.

Janssen also objected to the ruling, claiming it is inconsistent with the case management plan. This is false. Under the plan, Plaintiff is restricted from seeking field-level discovery related to territories other than Central Pennsylvania. That's it. In making the December 20 ruling, the Court did not misunderstand the case management plan.

Seeking to relitigate the ruling, Janssen also remarkably posits that it is "wildly out of step" with the proportionality standard. Here again, the Court considered the parties' arguments concerning the need for this discovery, including Janssen's arguments that it is disproportionate to the needs of the case. Requiring Janssen to produce documents possessed by current and former employees who had significant involvement and are known to possess relevant documents cannot constitute a manifest error of law, particularly in light of the importance of the issues at stake, the amount in controversy, that Janssen possesses all the documents, Janssen's

resources, and the importance of the discovery in resolving the issues.³

Because the Court did not misunderstand the case management plan nor make a manifest error of law, reconsideration of this ruling must be denied.

C. The Court Should Deny Reconsideration Of Its Ruling That Extended The Cut Off Date For Discovery Concerning IOI Support Programs Provided During Plaintiff's Employment That Janssen Continued Providing After She Left

The Court granted in part Plaintiff's motion requesting that Janssen be required to produce all requested documents that post-date February 2016. *See* ECF 237. In partially granting the request, the Court extended the temporal cut off for discovery concerning the IOI Support programs that Plaintiff provided to February 2020. *See id.* The Court explained that these documents are "relevant to the alleged kickbacks prior to February 2016 and recent information will be more readily available." *Id.* Conversely, the Court denied Plaintiff's request to be allowed to obtain discovery concerning any IOI Support programs that Janssen began providing after she left the company.

Once again, Janssen incorrectly asserts that this ruling must be reconsidered because the Court misunderstands the case management plan. In creating the plan, Chief Judge Saylor never ruled that Plaintiff is precluded from obtaining relevant discovery if such evidence pre- or post-dates Plaintiff's employment. Such a limitation would be contrary to law, undermine the truth-seeking process, and prevent resolution of the issues in dispute. To the contrary, Chief Judge Saylor made it clear during the October 22 conference that the parties are to take full discovery concerning all claims and defenses. Chief Magistrate Kelley did not misunderstand the plan.

Janssen's second objection is also not grounds for reconsideration. Disagreeing with the

³ Janssen's reliance on *Sustainable Sourcing, LLC v Brandstorm, Inc.*, 2017 WL 217747 (D. Mass. Jan. 18, 2017) is misplaced, as it is both procedurally and factually inapposite.

Court's conclusion, Janssen tries to relitigate whether discovery of documents and information that post-dates February 2016 is relevant and proportional to the claims and defenses.

From the numerous status reports, briefs, and hearings since last March, the Court is well apprised of why documents and information that post-date Plaintiff's employment are relevant. As Janssen highlights, Plaintiff explained to the Court that discovery that post-dates February 2016 is relevant to the issue of damages. But, as Plaintiff has also explained, and the Court is aware, the documents are also relevant for other reasons. For example, documents and information that post-date February 2016 are relevant to whether Janssen knew that providing the IOI Support was unlawful. The discovery will show what Janssen said and did in 2017 when this lawsuit brought to light its kickback scheme. *See* ECF 219 at 15. Discovery from more recent years will also be more accessible and employees will have clearer memories. *See id.* In the December 20 Order and during hearings (*see, e.g.,* Oct 18, 2021 Hearing Tr. (ECF 201) at 34:5-34:11), the Court specifically recognized the relevancy of this discovery.

In this matter, where the Court has taken a very active role in managing discovery and been asked to decide a steady stream of discovery disputes, the Court has been continuously assessing proportionality. Here again, the Court only partially granted Plaintiff's motion, maintaining significant limits on the post-2016 discovery that Plaintiff can receive. The ruling itself demonstrates that the Court did not make a clear legal error by not considering the proportionality of the post-February 2016 discovery to the needs of the case.

The Court understands the case management plan, and there was no manifest legal error. Consequently, reconsideration of this ruling should be denied.

D. The Court Should Deny Reconsideration Of Its Ruling That Plaintiff May Take Full Discovery Concerning The Scienter Elements Of Her Claims

To establish that Janssen violated the AKS, Plaintiff will have to show that Janssen

“knowingly and willfully” offered the IOI Support to physician practices to induce utilization or sales of Remicade and Simponi ARIA. *See* 42 U.S.C. § 1320a-7b(b)(2). Similarly, to establish that Janssen violated the FCA, Plaintiff must show that in providing the IOI Support Janssen “knowingly” caused the recipients to submit false claims to the Medicare program. 31 U.S.C. § 3729(a). Likewise, Janssen has asserted, among other defenses, that:

- Any false claims that it caused to be submitted were not done knowingly;
- It reasonably interpreted all applicable statutes and regulations; and
- It had a good faith belief that it was acting in compliance with the law.

See ECF 83 - Affirmative Defenses 8, 13 & 14. Accordingly, Janssen’s interpretations of the AKS and FCA and its knowledge concerning the legality of providing the IOI Support, including all relevant legal advice it received, are central issues. Indeed, through its affirmative defenses and stated reliance upon certain legal opinions, Janssen has taken affirmative steps that necessarily put at issue its knowledge concerning the legality of providing the IOI Support.⁴

In light of the Court’s updated instructions about the case management plan, including the specific directive to complete discovery on all elements of the claims and defenses (*see* October 22 Hearing Tr. (ECF 203) at 11:5-12:10), Plaintiff requested that the Court reconsider its earlier directives limiting Plaintiff’s ability to conduct full discovery of the scienter-related issues, such as discovery concerning any legal advice Janssen received, as well as any legal reviews it performed or received, concerning the legality of providing the IOI Support and related presentations. *See* ECF 219 at 19. As part of the December 20 Order (ECF 237), the Court granted the motion: “Relator is permitted to take full discovery concerning what it refers to

⁴ Plaintiff has filed a motion requesting that Janssen be ordered to produce all legal advice that it has received and legal reviews it has performed related to the legality of the IOI Support.

as the ‘the scienter element’ and Janssen is ordered to provide discovery of legal advice Janssen received and any legal reviews or analyses Janssen performed or received, that are not privileged. The court orders Janssen to provide a privilege log concerning this information.”

Janssen objects to this order, asserting that it is erroneous because Janssen has already produced numerous documents relevant to the scienter elements. While that is true, there are many other documents responsive to Plaintiff’s requests that Janssen has not produced. Most notably, Janssen has not produced the legal opinions, advice, and assessments that its attorneys and legal department provided concerning the legality of providing the IOI Support (nor has it provided a complete privilege log that identifies these critical documents). Also, Plaintiff is seeking additional discovery relevant to the scienter element through new document requests.

There was no mistake. The Court understands that Plaintiff has not received full discovery regarding the scienter elements. The Court should deny reconsideration of this ruling.

E. The Court Should Deny Reconsideration Of Its Ruling That Janssen Must Provide A Privilege Log Identifying Any Legal Advice It Received, As Well As Any Legal Reviews Or Analyses It Performed, Regarding The Legality Of The IOI Support

On October 18, the Court ordered Janssen to comply with its discovery obligations and provide a privilege log. *See* ECF 194. Janssen subsequently provided a partial 13-page privilege log that does not include the highly relevant legal opinions and advice it received or the legal assessments it performed and received concerning the lawfulness of the IOI Support. Recognizing that a privilege log is essential to the resolution of the issues in this case, as part of the December 20 Order (ECF 237), the Court yet again ordered Janssen to provide a privilege log identifying the highly relevant legal advice and any relevant legal assessments.

Janssen incredibly claims that in issuing this order the Court misunderstood the case management plan. Here again, there was no misunderstanding. The plan never relieved Janssen

from its obligation of having to provide a complete privilege log that includes disclosure of information necessary to the resolution of key issues in dispute. And this is not the first time Janssen has been ordered to provide a privilege log.

Janssen also baselessly asserts that the ruling constitutes a manifest error of law. Requiring a defendant to comply with the Federal Rules and provide a privilege log of the relevant legal opinions and legal reviews and analyses it has received cannot constitute a clear error of law. This is especially true here because one of the critical issues in the case is whether Janssen knew that providing the IOI Support to induce sales of Remicade and Simponi ARIA was unlawful. Moreover, Janssen has asserted an affirmative defense that it had a good faith belief that providing the IOI Support was lawful, putting at issue all the legal advice it received.

It bears emphasis that Janssen has had over a year to perform a reasonable inquiry of its legal department and attorneys to determine what legal opinions exist, what legal advice was received, and what legal reviews were performed. Janssen asserted its affirmative good faith defense in November 2020 (*see* ECF 83), presumably it understood the legal advice it had received when asserting the defense. Although it disregarded the orders, last April, the Court ordered Janssen to produce its legal analyses and evaluations (*see* ECF 120) and in October ordered it to provide a privilege log (*see* ECF 205). Further, Janssen recently reviewed the legal advice it received before disclosing its decision as to whether it will assert a reliance-upon-counsel defense. Janssen cannot be permitted to continue delaying providing a complete log.

IV. CONCLUSION

The Court should deny reconsideration of all its rulings in the December 20 Order.

Plaintiff requests oral argument on this motion.

Dated: January 28, 2022

Respectfully submitted,

/s/ Theodore J. Leopold

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CERTIFICATE OF SERVICE

I hereby certify on this 28th day of January, 2022, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Theodore J. Leopold

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